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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,657	12/01/2004	Hajime Yamada	P/2850-101	8759
2352 7590 06/12/2008 OSTROLENK FABER GERB & SOFFEN 1180 AVENUE OF THE AMERICAS NEW YORK, NY 100368403			EXAMINER LANDAU, SHARMILA GOLLAMUDI	
			ART UNIT 1611	PAPER NUMBER
			MAIL DATE 06/12/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/516,657	Applicant(s) YAMADA ET AL.	
	Examiner Sharmila Gollamudi Landau	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/1/04; 3/29/06</u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Receipt of Preliminary Amendment filed 3/20/06 is acknowledged. Claim 1 is pending. Claim 2 stands cancelled.

Information Disclosure Statement

The information disclosure statement filed 12/1/04 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites, "An external medicines for treating dermatitis: wherein a cyclodextrin including an adrenocortical steroid is dissolved in an aqueous solution containing polysaccharide; 0.025 to 0.5% by weight of the adrenocortical steroid, 0.2 to 30% by weight of the cyclodextrin, and 0.5 to 55% by weight of a dextran or pullulan are comprised; and 0.5 to 55% by weight of each xyloglucan, trehalose, laminaran, krestin, and pectin are blended; and the aqueous solution comprises at least one grape sugar, mutan, lentinan, sodium chloride, and potassium chloride." It is unclear if the recitation "wherein a cyclodextrin including an adrenocortical steroid is dissolved in an aqueous solution containing polysaccharide" is different

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from the composition containing "0.025 to 0.5% by weight of the adrenocortical steroid, 0.2 to 30% by weight of the cyclodextrin, and 0.5 to 55% by weight of a dextran or pullulan and 0.5 to 55% by weight of each xyloglucan, trehalose, laminaran, krestin, and pectin, and at least one grape sugar, mutan, lentinan, sodium chloride, and potassium chloride". It is unclear if the "polysaccharide" in line 3 is in addition to dextran or pullan or "dextran or pullan" is further defining the "polysaccharide" in line 3. The examiner suggests restructuring the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0780129 to Yamada et al in view of Griesbach et al (6,875,754) in view of JP 10025240 in further view of Schmidt et al (5,578,300).

Yamada et al teach a composition for dermatitis comprising an adrenal cortical steroid, cyclodextrin to solubilize the steroid, and water. The composition comprises 0.025-0.5% adrenal cortical steroid; 0.2-30% cyclodextrin; 0.5-55% of dextran or pullan; and an aqueous solution.

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The solution may further comprises glucose, mutan, lentinan, sodium chloride, and potassium chloride, and other polysaccharides.

Yamada et al do not teach xyloglucan (beta-glucan), trehalose, laminaran (beta-glucan), krestin (beta-glucan), and pectin.

Griesbach et al teach the use of water-soluble beta-glucans as therapeutic agents for skin diseases such as dermatitis, cradle cap, psoriasis, seborrhea sicca, seborrhea oleosa, psoriasis vulgaris, ichthyoses or UV erythemas. See column 3, lines 1-10. The glucans are used in an amount of 0.1-25% and preferably 0.5-15%. See column 3, lines 10-15. Specific glucan include krestin. See table 2.

JP '240 while teaching a bath agent teach the use of saccharides such as **glucose**, fructose, sucrose, mannitol, sorbitol, maltitol, xylitol, glucuronic acid, **trehalose**, alginic acid, hyaluronic acid, ribose, arabinose and deoxyribose. Ribose, arabinose and trehalose are preferred used in an amount of 1-100%. JP '240 teaches saccharides have skin moisture retention and are particularly suitable for treatment and prevention of skin diseases including **dermatitis**. See abstract.

Schmidt teaches a method of treating dermatitis using polysaccharides especially pectin in an amount of 0.05-0.5%. See abstract and column 2, lines 45-50.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Yamada et al, Griesbach, JP '240, and Schmidt et al and arrive at the instant invention. One would have been motivated to add beta-soluble glucans such as xyloglucan, laminaran, and krestin to Yamada's composition with a reasonable expectation of success since Greisbach teaches beta-glucans treat skin disorders such as dermatitis. One would have been motivated to also add pectin in the Yamada's composition with a reasonable

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expectation of success since Schmidt teaches polysaccharides such as pectin treat dermatitis and

Yamada suggests the incorporation of polysaccharides in addition to dextran or pullan.

Therefore, it is prima facie obvious to further include active compounds that treat dermatitis for an additive effect. Note In re Kerkhoven. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute Yamada's glucose with the instant trehalose. One would have been motivated to do so with a reasonable expectation of success since Schmidt teaches saccharides such as glucose and trehalose treat dermatitis. Therefore, it is prima facie obvious for a skilled artisan to substitute one functional equivalent agent for another since the prior art establishes its functional equivalency.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila Gollamudi Landau whose telephone number is (571) 272-0614. The examiner can normally be reached on Monday- Friday (8:30-6).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sharmila Gollamudi Landau/
Primary Examiner, Art Unit 1611